

REMARKS

This responds to the Notice of Non-Compliant Amendment mailed on June 1, 2005

The amendments to the claims made in the response filed 2 March 2005 were entered into the record. As a result, claims 1, 4, 7, 28, and 29 are pending. Applicant has reserved the right to re-introduce claims 2, 3, 5, 6, 8-27, and 30-47 in divisional applications and/or continuation applications at a later date. Applicant respectfully requests reconsideration of the above-identified application in view of the remarks that follow.

In the instant Office Action regarding the Notice of Non-Compliant Amendment, it is stated “[f]or clarification purposes, the examiner of record respectfully requests comments concerning the merits of the analysis and the Section 103 rejection presented in the Office Action dated 2 December 2004.” This response is provided in two parts. In part 1, a response to the grounds of rejection under section 103 of the claims of record as of the mailing of the Office Action on December 2, 2004 is provided. In part 2, the response filed 2 March 2005 with respect to the patentability of the amended claims over the cited references is copied into the instant response to the Notice of Non-Compliant Amendment for completeness.

Interview Summary

Applicant thanks Supervisor Examiner Nicholas Lucchesi for the courtesy of a telephone interview on 1 July 2005 with Applicant's representative David R. Cochran. The telephone discussion between Examiner Lucchesi and Applicant's representative, David R. Cochran, was in regards to the status of the pending claims. In particular, SPE Lucchesi stated that the amendments filed in the response to the Office Action prior to the instant Notice of Non-Compliant Amendment were entered into the record. A formal Interview Summary is also provided in a separate paper filed herewith.

PART 1.**First §103 Rejection of the Claims**

Claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Ellsworth (U.S. 3,325,061) or Maki (U.S. 4,252,159) in view of Fekl (U.S. 4,085,866). Applicant traverses these grounds for rejection of these claims.

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The *Fine* court stated that:

Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined only if there is some suggestion or incentive to do so." *Id.* (emphasis in original).

The M.P.E.P. adopts this line of reasoning, stating that

In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992). At the same time, however, although it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 USPQ 171, 174 (CCPA 1979)).

Applicant respectfully submits that the Office Action did not make out a *prima facie* case of obviousness for at least the following reasons:

(1) There is no suggestion to combine the cited references because a suggestion to combine must come from the prior art and not from Applicant's specification or impermissible hindsight; and

(2) The claimed invention has not been considered as a whole.

Lack Of A Suggestion To Combine The Cited References

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143. In the Office Action, it is noted that Ellsworth and Maki patents deal with syringes on which are numeric and volumetric indicia. The Office Action relies on Fekl regarding numeric non-volumetric indicia stating "the use of non-volumetric indicia is conventional in the art of dispensing as evidenced by the teachings of Fekl. Applicant submits that Fekl does not deal with the art of tools such as a syringe to dispense drug delivery in one action as in a syringe. Fekl provides a partially transparent container with indicia to view an amount of fluid dispensed over time. See *Fekl Summary*. Because of the dangers involved with the life of one to whom a syringe is applied, Application submits that a syringe is not conventional to the general art of dispensing. Applicant cannot find in the combination of Ellsworth or Maki and Fekl a teaching or suggestion that there is a reasonable expectation of success to the proposed combination of the Office Action. Applicant submits that it is not obvious that non-volumetric indicia on a syringe may be used to accurately and safely provide drug delivery in the manner provided by a syringe. Further, Applicant cannot find in the combination of Ellsworth or Maki and Fekl or in other references cited in the Office Action a teaching or suggestion that non-volumetric indicia on a syringe may be used to accurately and safely provide drug delivery. Without such a teaching or suggestion, Applicant submits that there is no reasonable expectation of success to make the combination of Ellsworth or Maki and Fekl as proposed in the Office Action.

The claimed invention has not been considered as a whole.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985); MPEP § 2141.02. Applicant submits that the proposed application of Fekl does not consider the invention of claim 1 as a whole. Fekl deals with a container which is partially transparent and has indicia to view an amount of fluid dispensed over time. *See Fekl Summary*. A container to dispense an amount of fluid over time is distinctly different from a syringe that delivers a drug using a plunger in a relatively short time frame. Because of these differences between Fekl's dispensing container and a syringe, Applicant submits that the instant rejections to claim 1 have applied references to different features of claim 1 and have not considered claim 1 as a whole.

Thus, for at least the reasons stated above, Applicant submits that the application of Ellsworth or Maki in view of Fekl does not establish a proper *prima facie* case of obviousness with respect to claim 1. Applicant respectfully requests withdrawal of these rejections of claim 1 and reconsideration of claim 1.

Second §103 Rejection of the Claims

Claims 4 and 28-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ellsworth or Maki in view of Fekl, Cohen (U.S. 3,747,847), and Ausman (U.S. 4,308,450). Applicant traverses these grounds for rejection of these claims.

Cohen deals with a slide rule guide. *See Cohen Summary*. Ausman deals with a two-piece calculator. *See Ausman Summary*. The combination of Cohen and Ausman does not provide a teaching or suggestion that non-volumetric indicia may be used on a syringe to deliver drugs. Therefore, Applicant submits that the combination of Cohen and Ausman does not cure the deficiencies of applying Ellsworth or Maki in view of Fekl to claim 1. Thus, Applicant submits that the application of Ellsworth or Maki in view of Fekl, Cohen, and Ausman does not establish a proper *prima facie* case of obviousness with respect to claim 1. Claim 4 and claims

28-30 are dependent on claim 1. For at least the reasons discussed herein with respect to claim 1, Applicant submits that the application of Ellsworth or Maki in view of Fekl, Cohen, and Ausman does not establish a proper *prima facie* case of obviousness with respect to claims 4 and 28-30. Applicant respectfully requests withdrawal of these rejections of claim 4 and 28-30 and reconsideration of these claims.

Third §103 Rejection of the Claims

Claim 7 was under 35 U.S.C. § 103(a) as being unpatentable over Ellsworth or Maki in view of Fekl, Cohen, Ausman, Alessi (U.S. 3,672,061), and Whitmire (U.S. 4,445,370).

Applicant traverses these grounds for rejection of these claims.

Cohen deals with a slide rule guide. *See Cohen Summary*. Ausman deals with a two-piece calculator. *See Ausman Summary*. Alessi deals with measuring an amount of liquid in a bottle. *See Alessi Objects of the Invention*. Whitmire deals with measuring oil in a tank. *See Whitmire Objects of this Invention*. Applicant submits that the combination of Alessi and Whitmire with the other references cited is improper, since there is no teaching or suggestion in the references for the combination. Applicant submits that though a syringe contains fluids (drugs to be dispense), a syringe is different subject matter from an oil tank and a bottle. In addition, no motivation or teaching has been provided from the cited references to combine the oil tank teachings of Whitmire and the bottle measuring teachings of Alessi with the other cited references.

Further, the combination of Cohen, Ausman, Alessi, and Whitmire does not provide a teaching or suggestion that non-volumetric indicia may be used on a syringe to deliver drugs. Therefore, Applicant submits that the combination of Cohen, Ausman, Alessi, and Whitmire does not cure the deficiencies of applying Ellsworth or Maki in view of Fekl to claim 1. Thus, Applicant submits that the application of Ellsworth or Maki in view of Fekl, Cohen, Ausman, Alessi, and Whitmire does not establish a proper *prima facie* case of obviousness with respect to claim 1. Claim 7 is dependent on claim 1. For at least the reasons discussed herein with respect to claim 1, Applicant submits that the application of Ellsworth or Maki in view of Fekl, Cohen, Ausman, Alessi, and Whitmire does not establish a proper *prima facie* case of obviousness with

respect to claim 7. Applicant respectfully requests withdrawal of these rejections of claim 7 and reconsideration of this claim.

Applicant respectfully submits that a response to all the grounds of rejection cited in the Office Action mailed 2 December 2004 have been provided herein.

PART 2.

REMARKS

Reconsideration and further examination of this application is hereby requested. Claims 1, 4, 7, 28, and 29 are currently pending in the application. Claims 2, 3, 5, 6, 8-27, and 30-47 have been canceled without prejudice to re-filing in a divisional application.

A. The Obviousness Rejections

Claim 1 has been rejected under 35 U.S.C. § 103(a) as being obvious over Ellsworth (U.S. 3,325,061) or Maki (U.S. 4,252,159) in view of Fekl (U.S. 4,085,866). Claims 4 and 28-30 have been rejected under 35 U.S.C. § 103(a) as being obvious over Ellsworth or Maki in view of Fekl, Cohen (U.S. 3,747,847), and Ausman (U.S. 4,308,450). Claim 7 has been rejected under 35 U.S.C. § 103(a) as being obvious over Ellsworth or Maki in view of Fekl, Cohen, Ausman, Alessi (U.S. 3,672,061), and Whitmire (U.S. 4,445,370). These rejections are respectfully traversed based on the following arguments.

In order for a patent claim to be obvious, the prior art must teach or fairly suggest each and every limitation of the claim. That is because the claim must be considered as a whole.

Independent claim 1 recites the limitation that the syringe has "a plurality of numeric non-volumetric measuring indicia" (refer to lines 2 and 3), while also reciting the limitation that the "syringe further comprises at least one additional different type of non-volumetric measuring indicia." (see claim 1 at the last three lines).

When considered together, the Ellsworth, Maki, Fekl, Cohen, Ausman, Alessi, and Whitmire references do not teach or fairly suggest a syringe that has plural numeric non-volumetric measuring indicia, and additionally having at least one additional different type of non-volumetric measuring indicia.

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10/074,009

Filing Date: February 14, 2002

Title: Per kilo doser

Page 9

Dkt: 1863.067US2

Due to this deficiency of the prior art, Applicant respectfully submits that the PTO has not established a *prima facie* case of obviousness with respect to claims 1, 4, 7, 28, and 29.

For the above reasons, applicant respectfully submits that the application is in condition for allowance with claims 1, 4, 7, 28, and 29. If there remain any issues that may be disposed of via a telephonic interview, the Examiner is kindly invited to contact the undersigned at the telephone number given below.

Applicant respectfully requests withdrawal of the rejections of the pending claims 1, 4, 7, 28, and 29, and reconsideration and allowance of these claims.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 371-2157 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

SAMUEL H. SLISHMAN

By his Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2157

Date 1 July 2005

By 
David R. Cochran
Reg. No. 46,632

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 1 day of July, 2005.

Name

KACIA LEE

Signature

